

REMARKS

Claims 1-20 are currently pending in the application, with claims 3, 4 and 15 being currently withdrawn from consideration due to a requirement for restriction and election of species. Claims 1-2, 5-14 and 17 are currently being amended, and claim 16 has been cancelled without prejudice of disclaimer. The foregoing separate sheets marked as "Listing of Claims" shows all the claims in the application, with an indication of the current status of each.

Election/Restriction

Applicant notes that as a result of requirements for election/restriction for the application, claims 3, 4 and 15 of the application have been withdrawn from consideration, and that the requirements have been made final.

Priority

Examiner notes that in order to claim priority based on a previously filed application, specific reference to the earlier filed application must be made in the present application. Accordingly, applicant has hereby amended the specification of the present application by inserting a paragraph referring to US provisional patent application 60/477,460, filed February 14, 2003. This prior provisional application was specifically identified in the declaration document executed by the inventor.

Applicant submits that this amendment does not add any new matter, being concerned entirely with priority, and respectfully requests entry of the amendment.

Specification

Examiner has objected to the specification due to the use of a reference to an appendix in the paragraph at lines 10-16 on page 12 of the application ("App.2,3"). Applicant has hereby amended the specification to replace this paragraph with a replacement paragraph in which the reference to the appendix has been removed.

Applicant submits that this amendment does not constitute the addition of new matter to the application, but rather involves removing a phrase from the specification. Applicant respectfully requests entry of the amendment.

Claim Rejections: 35 U.S.C. § 112, first paragraph

Claims 1-14 and 16-20 stand rejected under 35 U.S.C. § 112, first paragraph, due to lack of enablement. Claim 16 has hereby been cancelled, thereby making moot that portion of the rejection.

Claims 1-14 and 17-20, as amended, are directed to a composition and method for eliciting an immune response. Applicant herewith submits concurrently herewith a declaration of the inventor, David Hone, that includes experimental data obtained with a composition comprising the elected species, i.e. with a least one genetic sequence encoding a mART derived from cholera toxin containing the L41F mutation, and at least one genetic sequence encoding an antigen. Specifically, the mutant mART containing the L41F mutation is CtxA1_{S41Y}, and the antigen is HIV-1_{MN} gp120. As can be seen from the data, and particularly with reference to Figure 1, serum ELISAs demonstrated that the compositions containing DNA encoding CtxA1_{S41Y} display substantive adjuvant activity and augment both the magnitude and persistence of the serum IgG response to gp120, in comparison to the control composition. Further, no adverse (toxic) affects were observed at the immunization sites.

Claims 1-2, 5-14 and 17 have been amended to recite elicitation of an immune response, making moot Examiner's assertion that a vaccine has not been enabled. Clearly, an immune response is elicited with the elected species. Thus, the declaration demonstrates that the claimed invention is fully enabled by the specification. Further, Applicant notes that the Examiner's concerns regarding toxicity of the composition are answered in that no adverse side effects were observed as a result of administration of the composition. One of skill in the art would expect that vectors other than a plasmid would be equally successful when used in the composition or method. Applicant submits that the immune system will raise antibodies to gp120 when presented with a CtxA1 L41F mutant regardless of the precise source of the genes that encode the two species. So long as the two species are both presented to the immune system, one of skill in the art would reasonably expect successful results with viral vectors, retroviral vectors, naked DAN and naked RNA.

In addition, Applicant submits that the substitution of one promoter for another in the practice of the invention would be substantially a matter of convenience and/or preference for

one of skill in the art. Shuffling of genetic elements such as promoters is well known and would not place an undue burden of experimentation on a practitioner of the invention.

Gp120 is the antigen that was utilized in the experiments. However, one of skill in the art would recognize that the mechanism of eliciting an immune response is well known and includes similar pathways for all antigens. Thus, contrary to Examiner's assertion, results obtained with gp120 are representative of results that one of skill in the art could reasonably expect to obtain with other antigens.

In view of the foregoing, it is requested that the application be reconsidered, that claims 1-14, 15 and 17-20 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: ruth@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

If an extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Ruth E. Tyler-Cross', with a long horizontal flourish extending to the right.

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